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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,547	07/29/2003	Mark T. Marshall	P-11313.01	7482

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EXAMINER	
FLORY, CHRISTOPHER A	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/630,547	MARSHALL ET AL.	
	Examiner	Art Unit	
	Christopher A. Flory	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *29 July 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/19/04 & 1/16/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "25" and "26" have both been used to designate first electrode (paragraph [17]). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "25" has been used to designate both first electrode and second electrode ([17]). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and

informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to because Figure 3C is not of sufficient quality to effectively illustrate a porous layer made of collagen as described in the specification. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-10, 14-18, 22, and 25-27 of copending Application No. 10/439,201. Although the conflicting claims are

not identical, they are not patentably distinct from each other because the component of a second elongated lead body in the instant application does not distinguish over the device in the copending application because it shares a common functionality, and a device with a first and second lead bodies is a reasonable embodiment of copending invention. It is well known in the field that medical lead electrodes can be placed either adjacent to each other on one lead body when intended for placement within the same chamber (e.g. the right ventricle) or placed each on its own lead body for the sake of placement across different barriers of the heart (e.g. one in the right ventricle and the other in a cardiac vein), both embodiments being for the purpose of pacing/sensing in a localized region of the heart. There are several examples of both configurations cited by the examiner on form PTO-892 Notice of References Cited.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. Claims 1-20 are provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending Application No. 10/439,201 which has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the copending application, it would constitute prior art under 35 U.S.C. 102(e), if published under 35 U.S.C. 122(b) or patented. This provisional rejection under 35 U.S.C. 102(e) is based upon a presumption of future publication or patenting of the copending application.

Figure 4A of copending Application No. 10/439,201 shows a medical system comprising an implantable medical device with a first elongated lead body (7); a second elongated lead body (350); a first electrode adapted for intimate contact with tissue at an implant site (13); a second electrode joined to the second lead body (355); an isodiametric porous layer formed over the second electrode (paragraph [23]); wherein the first electrode is implanted in the right ventricle and the second electrode is capable of being implanted in the cardiac vein; and further comprising a high voltage electrode joined to the second lead body (14). Claims 3-16 are also clearly anticipated by the copending application.

This provisional rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the copending application was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131. This rejection may not be overcome by the filing of a terminal disclaimer. See *In re Bartfeld*, 925 F.2d 1450, 17 USPQ2d 1885 (Fed. Cir. 1991).

8. Claims 1-10, 16-18 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Carson (US Patent Number 5,931,862).

Regarding claims 1-2 and 20, Carson'862 shows a medical electrical lead (Fig. 1, lead 12) comprising an elongated body with a first elongated insulated conductor, a second elongated insulated conductor (column 4, lines 52-63) and a connector with a first and second electrical contact formed at a proximal end (connectors 22 and 24); a first low voltage electrode adapted for intimate contact with tissue to provide pacing stimulation (Figs. 2 & 3, distal pacing electrode 20, helical coil or tined formations); a second low voltage electrode joined to the lead body in proximity to the first electrode (underlying electrode 16); and a porous layer formed over the second electrode (porous tubular covering 10); wherein the outer surface of the second electrode (16) is recessed from the outer surface of the lead body (Fig. 2) and the outer surface of the porous layer (10) is isodiametric with the outer surface of the lead body (column 2, lines 39-44).

Regarding claims 3-10, Carson'862 discloses that the porous layer may comprise silicone, polyurethane, expanded PTFE, or collagen (column 2, lines 39-53; column 5, lines 10-23); and a means to promote wetting comprising a wetting agent which can be a surfactant and a surface treatment of the porous layer (column 2, line 54 through column 3, line 26).

Regarding claim 16, Carson'682 discloses the invention as previously recited wherein the porous layer is adapted to prevent chronic tissue ingrowth (column 2, lines 47-48).

It is noted that the component of a second elongated lead body in the instant application does not distinguish over the device of Carson'682 because it shares a common functionality, and a device with a first and second lead bodies is a reasonable embodiment of the Carson'682 system, where connector branches 22 and 24 with porous coverings 10' and 10" could extend for the full length of the device and in such a configuration constitute a first and second lead body, each containing one of the pacing/sensing electrodes and capable of being implanted in the cardiac vein or the right ventricle (as shown in Figure 1).

9. Claims 1-10, 11,16 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Krall et al. (WO 02/089909 A1).

Regarding claims 1-2 and 20, Krall et al. shows a medical electrical lead (Fig. 1, lead body 6) comprising an elongated body with a first elongated insulated conductor, a second elongated insulated conductor (Fig. 2 coiled electrical conductor 14, second electrical conductor 16) and a connector with a first and second electrical contact formed at a proximal end (connectors 4); a first low voltage electrode adapted for intimate contact with tissue to provide pacing stimulation (Fig. 2, distal tip electrode 10); a second low voltage electrode joined to the lead body in proximity to the first electrode (coiled electrode portion 8, coiled electrode 24); and a porous layer formed over the second electrode (porous thin film 30); wherein the outer surface of the second electrode (24) is recessed from the outer surface of the lead body (Fig. 2) and the outer surface of the porous layer (30) is isodiametric with the outer surface of the lead body (column 2, lines 39-44).

Regarding claims 3-10,11 and 16, Krall et al. discloses that the cover comprises a porous polymer (claim 1), preferably ePTFE (claim 8); is relatively thin, on the order of .13mm (or .005inches) thick (page 3, lines 5-6; page 10, lines 26 through page 11, line 4); is adapted to prevent chronic tissue ingrowth (page 3, lines 10-13); and comprises a means of wetting (claims 13-14, surfactant polyvinyl alcohol).

It is noted that the component of a second elongated lead body in the instant application does not distinguish over the device of Krall et al. because it shares a common functionality, and a device with a first and second lead bodies is a reasonable embodiment of the Krall et al. system, where connectors (4) could extend for the full length of lead assembly (2) and in such a configuration constitute a first and second lead body, each containing one of the pacing/sensing electrodes and capable of being implanted in the cardiac vein or the right ventricle (as shown in Figure 1).

10. Claims 1-5 and 16-20 rejected under 35 U.S.C. 102(e) as being anticipated by Belden (US Patent 6,847,845).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Regarding claims 1-5 and 16-20, Belden'845 discloses a medical system comprising an implantable medical device (80); a first elongated lead body (10)

implanted in a cardiac vein with a first electrode (12) adapted for intimate contact with tissue and a second electrode (16) with a porous layer (32) formed over the second electrode which may be isodiametric and comprised of ePTFE, silicone, or polyurethane (column 3, lines 20-25, 47-56) and adapted to prevent chronic tissue ingrowth (column 3, line 64 through column 4, line 5); a second elongated lead body (70) implanted in the right ventricle (column 5, lines 54-67) with a second electrode (72); and comprising a third high voltage electrode adapted for defibrillation stimulation (defibrillation coil 74).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 11-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carson in view of Hull et al. (US Patent 5,269,810).

Carson'862 shows the invention substantially as claimed in paragraph 8 above, but does not disclose the thickness of the porous layer (2-9 mm) or the desired size range for the pores in that layer (0.4-50 microns).

In the same problem solving area, Hull et al. teaches an electrode-covering layer made of conductive porous PTFE that is about 0.13 mm (0.005 inches) thick with fibril length (i.e. internodal distance and pore size) of 10 microns for the advantages of being highly biocompatible, highly flexible, and long-lasting (column 3, lines 32-45; column 4, lines 1-15).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use similar structural criteria with the Carson'862 invention for the same advantages of biocompatibility, flexibility and long lifespan (motivation to combine provided by Hull et al., column 3, lines 32-45; column 4, lines 1-15).

14. Claims 12-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carson in view of Soukup et al. (US Patent 5,466,252).

Carson'862 shows the invention substantially as claimed in paragraph 8 above, but does not disclose the desired size range for the pores in that layer (0.4-50 microns).

In the same field of endeavor, Soukup et al. teaches an implantable lead with a porous PTFE layer with preferred fibril lengths greater than 4 microns, and most preferably greater than 10 microns to provide the necessary amount of flexibility and extensibility for the intended application and to present an acceptable biocompatible surface to the blood chemistry to which the outer surface of the lead will be exposed (column 2, lines 26-34).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use similar parameters for the lead body covering in the Carson'862 invention to provide the same advantages of flexibility and biocompatibility (motivation to combine provided by Soukup et al., column 2, lines 26-34).

15. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Carson in view of Kroll (US Patent 6,327,498).

Carson'862 shows the invention substantially as claimed in paragraph 8 above, but does not disclose a third high voltage electrode adapted for defibrillation stimulation.

In the same field of endeavor, Kroll'498 teaches a third electrode (Fig. 2, electrode 46) placed proximal to a second electrode (32) and distal to a first electrode (34) for the purpose of providing shocking stimulation pulses (column 7, lines 64-67).

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include a third electrode in the Carson'862 device for the same advantage of applying shocking stimulation (defibrillation) to the heart (motivation to combine provided by Kroll'498 column 7, lines 64-67).

George Manuel
Primary Examiner